IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PADDOCK LABORATORIES, INC.,

Plaintiff, **CASE NO.:**

v. **HON.**

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Defendant.

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COMPLAINT AND JURY DEMAND

NATURE OF THE CASE

1. Defendants obtained approval to market a diabetes drug called Prandin® in 1997. After enjoying twelve years of market exclusivity for this product, Defendants' patent protection for Prandin® was set to expire in 2009. Faced with the threat of losing most of their Prandin® franchise to competition from generic manufacturers soon after that date, Defendants engaged in a two-phased strategy to unlawfully extend their monopoly at the expense of Plaintiff Paddock, other potential generic competitors and, importantly, all consumers of this drug. The harm to consumers of this drug, which enjoys approximately $150 million in annual sales, is likely to be in the hundreds of millions or more should Defendants be permitted to continue to carry out their plan.

2. Defendants sought to fulfill this scheme by manipulating the FDA regulatory process, and in particular the process by which potential generic competitors certify to the FDA with respect to patents listed in the FDA's Orange Book for Prandin®. As detailed below, Paddock and other generic competitors are seeking FDA approval for repaglinide (the generic name for the active ingredient in Prandin®) alone – that is, repaglinide itself, not in combination with any other drug. Repaglinide lost its patent protection in 2009. Defendants' sole

remaining patent relating to repaglinide covers only the use of repaglinide in combination with another drug, metformin, and does not cover repaglinide itself. Nonetheless, to prevent generic competitors from receiving approval to sell repaglinide, Defendants first tried to impede competition by filing a "citizen petition" with FDA in June 2008. Defendants' citizen petition requested that the FDA require all generic manufacturers seeking approval for repaglinide to modify their labeling to include a combination therapy (repaglinide plus metformin) even though the generic competitors did not seek to market such a combination. Such a labeling change would have forced all such potential competitors improperly to be subject to a 30-month stay of FDA approval of their generic repaglinide products and face other impediments to the approval of their products.

3. Defendants' initial plan failed. The FDA rejected Defendants' citizen petition in December 2008. The FDA found that generic companies were not required to refer to the combination therapy in their labeling, and that omission of such information would not impact the safety and effectiveness of a generic repaglinide product.

4. Promptly after the FDA rejected their first attempt, Defendants launched the second phase of their scheme, which is the focus of the present Complaint. Defendants submitted to the FDA a new use code for the sole patent listed in the FDA's Orange Book for Prandin®. A use code is a description that a brand manufacturer submits for a "method of use" patent that is listed in the Orange Book, which describes what FDA-approved use the patent claims.

5. The FDA relies on the brand manufacturer's "use code" description to determine what certifications the FDA will accept for the associated patent.

6. Defendants' newly submitted use code misrepresented to the FDA that the sole remaining patent for Prandin® covers all approved uses of repaglinide, including repaglinide monotherapy, when in fact the patent solely claims the use of repaglinide in combination therapy with metformin. Defendants' misrepresentation forced all generic manufacturers, including Paddock, to certify whether or not they infringed this patent, even though Paddock

did not seek approval for combination therapy. By compelling this certification – called a "Paragraph IV Certification" – Novo Nordisk unlawfully delayed generic competition by : (i) preventing generic competitors from submitting the narrowed labeling omitting the information on the combination with metformin; (ii) filing a patent suit based on the combination patent – regardless of its lack of merit – and obtaining an automatic 30-month stay of approval of all potential generic competitors; and (iii) preventing any applicant who, like Paddock, is not a "first applicant" as defined in the statute from receiving approval until 180 days after a "first applicant" obtains approval for and begins selling its product. The combination of these factors has delayed generic approval, and will continue to delay generic approval, for many months or years absent the intervention of this Court.

7. Defendants' scheme has wide-ranging implications. The laws governing pharmaceutical products balance the need to provide new drug innovators who patent their products a reasonable economic return, against consumers' need for access to lower-priced generic products. Defendants' scheme stands out in seeking to alter that balance through illegal means. This kind of conduct has been the focus of private litigation and has gained attention from the U.S. Federal Trade Commission, which has targeted manipulation of the FDA regulatory process by branded pharmaceutical companies. If Defendants can automatically extend their monopoly by misrepresenting the nature and scope of their patents, as done here, nothing will prevent other drug manufacturers from doing the same. In the meantime, repaglinide consumers will suffer by being forced to continue to pay monopoly prices. For the reasons stated below, Defendants' scheme violates both federal and state antitrust laws.

JURISDICTION AND VENUE

8. Paddock Laboratories, Inc. ("Paddock") brings this action under the antitrust laws of the United States, including Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, and under the Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.773.

9. Defendants have engaged in the sale of Prandin® in interstate commerce and in this judicial district. At all material times, Prandin®, manufactured and sold by Defendants, was shipped across state lines and sold to customers located outside the state of manufacture. In connection with the purchase and sale of Prandin®, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines. In addition, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of the Defendants as charged in this Complaint were within the flow of, and have substantially affected, interstate commerce.

10. This Court has subject matter jurisdiction over the federal antitrust law claims under 28 U.S.C. § 1331 and 1337(a). This Court also has subject matter jurisdiction over the state law claims under 28 U.S.C. § 1367.

11. Defendants may be found, transact business, and are subject to personal jurisdiction in the Eastern District of Michigan.

12. The violations of law alleged in this Complaint took place, in part, in the Eastern District of Michigan and have injured Paddock in this district. Venue is therefore proper in this judicial district pursuant to 15 U.S.C. §§ 15 and 22; and 28 U.S.C. § 1391.

THE PARTIES

13. Plaintiff Paddock is a corporation organized and existing under the laws of the State of Minnesota, having its principal place of business at 3940 Quebec Avenue N, Minneapolis, Minnesota 55427.

14. Defendant Novo Nordisk, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

15. Defendant Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, having its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

HATCH-WAXMAN STATUTORY AND REGULATORY BACKGROUND

16. The FDA regulates the approval, manufacture, and commercial sale of pharmaceuticals in the United States pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act"), which was first passed in 1938. No branded or generic pharmaceuticals may lawfully be sold commercially in the United States without FDA approval. Congress passed the "Hatch-Waxman Amendments" to the Act in 1984 to simplify and shorten the approval process for generic drugs that have the same active ingredient as a corresponding branded drug.

17. The Hatch-Waxman Amendments permit generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that expedites the drug approval process. Rather than go through full clinical trials, as is required for a branded drug, an ANDA filer need only show that its drug is bioequivalent (within a defined range) to a branded drug that the FDA has already approved. If the generic drug is bioequivalent and is the same dosage strength and form as the branded drug, it is deemed to be an "AB-rated equivalent" to the branded drug.

18. The manufacturer of a branded drug is required to submit to the FDA the patent numbers and expiration dates for all patents that the branded drug manufacturer asserts cover the branded drug or an approved use of the branded drug. The FDA, without review, publishes the submitted information in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").

19. Once a patent is listed in the Orange Book, an ANDA applicant who seeks approval before the patent expires must pursue one of two statutory provisions: a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), or a statement under 21 U.S.C. § 355(j)(2)(A)(viii) (a "Section viii Statement").

20. If an ANDA applicant seeks approval to market a drug for which one or more method of use patents are listed in the Orange Book and the ANDA applicant does not seek approval for uses claimed by such patents, the ANDA must include a Section viii Statement that the method of use patent does not claim any of the proposed uses for which the applicant seeks

approval. 21 U.S.C. § 355(j)(2)(A)(viii). An ANDA applicant filing a Section viii Statement must omit from its labeling information pertaining to the uses claimed by the method of use patent. The method of use patent claiming the uses omitted in the labeling will thus not act as a barrier to approval of the ANDA by the FDA.

21. If a listed patent is not a method of use patent, or if the ANDA applicant seeks approval for a use that is claimed in a listed method of use patent, the ANDA must contain a Paragraph IV Certification that each such patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). An ANDA applicant who files a Paragraph IV Certification must send a "notice of certification" to the owner of the listed patent and the NDA for the branded drug.

22. Unlike the submission of a Section viii Statement, the filing of a Paragraph IV Certification permits the holder of any patent listed in the Orange Book to assert a cause of action for patent infringement against the ANDA applicant. If the branded drug manufacturer sues within 45 days from receipt of notification of any Paragraph IV Certification, the FDA cannot grant final approval of the ANDA until the earlier of (i) 30 months from the patent holder's receipt of notification of the Paragraph IV Certification; or (ii) the date on which final judgment is entered in the patent infringement case holding such patent invalid, not infringed, or unenforceable. In practice, this means that a manufacturer of a branded drug can automatically prevent entry of a generic drug for 30 months simply by filing and maintaining a patent infringement litigation, regardless of whether its patent infringement claim has merit. In addition, if an ANDA applicant is not a "first applicant" as defined in the statute, the ANDA will not be approved until 180 days after the first marketing of the drug by a "first applicant." This has the potential to delay competition for many years.

23. The ANDA applicant can sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval.

24. Neither the 30-month stay period, nor the 180-day exclusivity period applies to an application that has a Section viii Statement rather than a Paragraph IV Certification and,

therefore, these provisions do not have the potential to delay competition from applicants seeking FDA approval through a Section viii Statement.

BENEFITS OF GENERIC COMPETITION

25. FDA-approved generic drugs are identical to their branded equivalents in therapeutic effects and safety, and are, therefore, interchangeable.

26. Typically, generic drugs are initially priced anywhere from 30 to 90 percent or more below the price of the branded drug for which they are approved with an AB rating. As a result, the branded drugs lose market share to their competing generic equivalents. As more generic manufacturers enter the market, prices for generic drugs decrease even more, while the branded drug continues to lose more of its market share. This price competition benefits all purchasers of the drugs who are able to (a) buy the generic equivalent at substantially lower prices, and/or (b) obtain lower prices for the branded drug once generic drugs enter the market.

27. Generic drug competition generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the corresponding branded drugs. A 2004 FDA study found that patients whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. Moreover, the number of generic drug companies, the number of ANDAs filed, and consequently the number of generic drug options on the market have all increased dramatically since the adoption of the Hatch-Waxman Act in 1984. Accordingly, savings to consumers have also increased.

28. Faced with the prospect of such price competition, branded drug manufacturers have an incentive to hamper the ability of generic manufacturers to enter a market. For instance, if a branded drug manufacturer can cause the FDA to list other related patents in the Orange Book, the generic manufacturers must file certifications as to these newly listed patents. These certifications, in turn, allow the branded drug manufacturer an opportunity to sue the generic manufacturer for patent infringement and obtain a 30-month stay.

29. This delay occurs regardless of the lack of merit of the patent suit and/or the Orange Book listing. Thus, the very listing in the Orange Book can give the branded drug manufacturer the ability to forestall FDA approval of generic products and to force generic manufacturers into costly and time-consuming patent litigation before selling their generic products in competition with the branded drug.

BACKGROUND ON PATENT USE CODES

30. Manufacturers of branded drugs must submit to the FDA certain information concerning "any patent which claims the drug [or] . . . a *method of using such drug* and with respect to which a claim of patent infringement could reasonably be asserted." 21 U.S.C. § 355(b)(1)(G) (emphasis added). This information is published in the Orange Book. FDA regulations require the branded manufacturer to submit for each method of use patent information on "[w]hether the patent claims one or more approved methods of using the approved drug product and a *description of each approved method of use or indication* and related patent claim of the patent being submitted." 21 C.F.R. § 314.53(c)(2)(ii)(P) (emphasis added). The branded manufacturer must "*separately identify each pending or approved method of use* and related patent claim" and must further "identify with specificity the section of the approved labeling that corresponds to the method of use claimed by the patent." 21 C.F.R. § 314.53(b)(1). The description is known as a "use code."

31. The FDA accepts any use code submitted by the branded manufacturer without factual inquiry, assuming its accuracy and specificity. Indeed, the FDA does not construe patents, but undertakes only a ministerial role in listing any method of use patent and any corresponding use code that a branded manufacturer submits. The FDA relies solely upon the signed verification by the branded manufacturer. The branded manufacturer must attest under penalty of perjury that its submission of the patent information, including the use code, to the FDA is "true and correct." 21 C.F.R. § 314.53(c)(2)(ii)(R).

32. The FDA and ANDA applicants look to the use code when an ANDA applicant submits a Section viii Statement. The FDA will not accept a Section viii Statement if the ANDA

applicant's proposed label contains the use identified in the description in the use code. In its instructions for submitting patent information, the FDA clearly requires that branded manufacturers provide accurate and specific representations with respect to their proffered use code descriptions:

> The use code designates a method of use patent that claims the approved indication or use of a drug product. Each approved use claimed by the patent should be separately identified . . . and contain adequate information to assist . . . ANDA applicants in determining whether a method of use patent claims a use for which the . . . ANDA applicant is not seeking approval.

FDA Form 3542.

RELEVANT MARKET AND MARKET POWER

33. The relevant market in which to assess the anticompetitive effects of Defendants' conduct concerning Prandin® is the market for repaglinide tablet products, including Prandin® and bioequivalent, FDA-approved generic repaglinide tablet products.

34. The generic repaglinide tablet product developed by Paddock will be, upon final FDA approval, an AB-rated equivalent to Prandin®, which means it will be considered bioequivalent to Prandin.® Repaglinide tablet products, including Prandin®, are not reasonably interchangeable with other products due to, for example, price, use, qualities, characteristics, and/or distinct customers or end uses. The availability of other treatments for improving glycemic control in adults with type 2 diabetes mellitus also is not sufficient to prevent the anticompetitive effects of Defendants' conduct.

35. Generic repaglinide tablet products would be priced substantially below the price Defendants charge for Prandin®. Upon entry of AB-rated generic repaglinide tablet products, these products would divert substantial sales from Prandin®, which would benefit consumers, patients, and government programs (such as Medicare and Medicaid).

36. Because of this competitive relationship between branded drugs and their generic competitors, such products comprise a distinct relevant product market for antitrust purposes. Thus, the relevant product market in which to assess the anticompetitive effects of Defendants' conduct is the market for Prandin® and its AB-rated equivalents (the "Relevant Market").

37. The relevant geographic market in which to assess the anticompetitive effects of Defendants' conduct is the United States. FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

38. There are substantial barriers to entry into the Relevant Market, including FDA's regulatory requirements and the substantial time and expense required to develop an AB-rated equivalent to Prandin®.

39. Defendants are the only company with an FDA-approved repaglinide product. As a result, at all times relevant to this Complaint, Defendants have possessed monopoly power in the Relevant Market with a market share of 100 percent.

FACTUAL ALLEGATIONS

Background on Prandin® and Related Patents

40. In 1997, Defendant Novo Nordisk, Inc. obtained approval via a New Drug Application ("NDA") to market repaglinide under the brand name Prandin®.

41. Prandin® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

42. Prandin® is approved by the FDA for three uses: (1) repaglinide by itself (i.e. monotherapy); (2) repaglinide in combination with metformin; and (3) repaglinide in combination with thiazolidinediones.

43. Defendants are the owners or assignees of, or have rights in, two patents related to repaglinide: (1) U.S. Patent No. RE37035 ("RE'035"); and (2) U.S. Patent No. 6,677,358 ("'358 patent").

44. RE'035 claimed the compound repaglinide and expired on March 9, 2009.

45. The '358 patent claims the use of repaglinide in combination with metformin and expires on June 12, 2018. Specifically, the '358 patent claims: "A method for treating non-

insulin dependent diabetes (NIDDM) comprising administering to a patient in need of such treatment repaglinide in combination with metformin."

Defendants' Attempt to Manipulate FDA "Citizen Petition" Process

46. With the March 2009 expiration of RE'035 approaching, Defendants had to act swiftly to protect their repaglinide monopoly. While the '358 patent did not expire until 2018, this patent gave Defendants the right to prevent competitors from using repaglinide only in combination with metformin, and not from using repaglinide itself. In other words, without taking action, Defendants could not prevent competition from ANDA applicants, such as Paddock, seeking to market repaglinide itself.

47. To prevent the erosion of their Prandin® profits through competition with lower-priced generic alternatives, in June 2008, Defendants submitted a citizen petition to the FDA requesting that the FDA refrain from approving any ANDA relating to Prandin® that omitted information on combination therapy with repaglinide and metformin.

48. If successful, this tactic by Defendants would have forced ANDA applicants to include in their labeling language regarding combination therapy with repaglinide and metformin, even if the ANDA applicants wished only to market repaglinide itself. The change in labeling would, in turn, force the ANDA applicants to file a Paragraph IV Certification with respect to the '358 patent, giving Defendants grounds for filing a patent infringement suit.

49. A timely filed infringement suit would trigger a 30-month stay of approval, thus creating a statutory bar to final approval, delaying entry of competition into the market and generating needless litigation costs for the ANDA applicant. It would also subject all ANDA applicants who were not "first applicants" to the 180-day exclusivity of any first ANDA applicant.

50. Defendants' first scheme to prevent generic competition to repaglinide failed. In December 2008, the FDA rejected Defendants' citizen petition, determining that the omission of information on metformin combination therapy would have no effect on the safety and efficacy

of a repaglinide generic product and, therefore, information for the combination therapy did not need to be included in the generic applicants' labels.

51. In addition, the FDA advised that a Section viii Statement would be an appropriate submission for the '358 patent method of use claims. Such a submission would allow ANDA applicants for generic repaglinide to enter the market upon expiration of the RE'035 patent in March 2009.

Defendants' Manipulation of the FDA's Use Code Procedures and Requirements

52. Unable to protect their repaglinide monopoly through the citizen petition process, Defendants, in May 2009, deceptively manipulated the use code for the '358 patent. The original use code (U-546) appropriately tracked the language of the '358 patent's method claim, describing the patented method of use as the "use of repaglinide in combination with metformin to lower blood glucose." But Defendants substituted the original use code with an altered use code (U-968) that states that the patent claims "a method for improving glycemic control in adults with type 2 diabetes mellitus," without any mention of metformin, even though all of the claims of the '358 patent require metformin.

53. The altered use code is so broad that it incorrectly represents that the '358 patent covers *all three* approved uses of repaglinide—repaglinide monotherapy, repaglinide in combination with metformin, and repaglinide in combination with thiazolidinediones. Of course, as is clearly stated in claim four (4) of the '358 patent, the '358 patent claims only *one* approved use of repaglinide—repaglinide in combination with metformin. In submitting the altered use code, Defendants have improperly misrepresented to the FDA that the '358 patent covers uses for which Defendants have no patent protection and for which Defendants have no lawful right to exclude potential competitors.

54. Importantly, Defendants were neither required nor directed by the FDA to change their use code for the '358 patent.

55. Indeed, Defendants admitted to this Court that the use code alteration was, in part, designed to prevent an ANDA applicant seeking to market lower-priced generic Prandin® from

carving out metformin combination therapy information from its labeling. *Novo Nordisk A/S v. Caraco Pharmaceutical Laboratories, Ltd.*, 649 F. Supp. 2d 661, 664 n.5 (E.D. Mich. 2009).

56. Notably, Defendants did not alter the use code for the '358 patent in connection with their Prandimet® product, for which the '358 patent is also listed. Prandimet® tablets contain both repaglinide and metformin. Unlike changing the use code for Prandin®, changing the use code for Prandimet® would provide no benefit to Defendants since ANDA applicants would be unable to carve out reference to the use of repaglinide with metformin in the combination Prandimet® product.

Defendants' Conduct Forces Paddock to Submit a Paragraph IV Certification Providing Defendants with Improperly Obtained 30-Month Stay of Generic Competition and 180-Day Period of Limited Generic Competition

57. Defendants' manipulation of their use code for the '358 patent was designed to – and has had the effect of – delaying generic competition to Prandin®. The change prevented Paddock, and other repaglinide ANDA filers, from seeking approval under section viii, and forcing them instead to file a Paragraph IV Certification with respect to the '358 patent.

58. Paddock submitted to the FDA an ANDA on repaglinide. Paddock included in its ANDA a Section viii Statement for the '358 patent's method of use claim, carving out from its proposed label information with respect to the combination therapy with metformin. Paddock submitted the Section viii Statement because Paddock sought approval to market generic repaglinide, with an amended label that would exclude any information regarding combination therapy with metformin.

59. A Section viii Statement was appropriate because the '358 patent does not have claims that encompass the repaglinide uses for which Paddock is seeking approval, and because the FDA has determined that safety and efficacy are not impacted by excluding information relating to metformin combination therapy from the label for repaglinide.

60. Defendants' recently-altered use code tied the FDA's hands with respect to its ability to approve Paddock's (or any other generic ANDA applicant's) ANDA containing a Section viii Statement. Because Defendants manipulated their use code to delete any mention of

metformin and Defendants knew that the FDA relied on the use code in a ministerial fashion to determine whether to accept a Section viii Statement, Defendants knew that the altered use code would prohibit generic applicants from carving any information out from the labeling. As the FDA explained to Paddock in May 2010, while the previously listed method of use code for the '358 patent (use of repaglinide in combination with metformin to lower blood glucose) allowed for the carve out of metformin, that use code was no longer listed, and therefore it would not be possible for Paddock to delete metformin information from the labeling.

61. The FDA's role in administering the Orange Book is ministerial. It does not interpret patents or police Orange Book listings – rather it simply takes, as given, patent information provided by brand manufacturers. Thus, the FDA did not have discretion, as it did in rejecting Defendants' citizen petition, to reject Defendants' improper change to the use code for the '358 patent.

62. Similarly, the FDA did not have discretion to approve Paddock's Section viii Statement in light of Defendants' manipulative scheme to wrongfully extend its repaglinide monopoly beyond the scope of the relevant patents. The FDA may only approve a Section viii Statement where no overlap exists between the proposed amended label submitted by the generic manufacturer and the use code narrative submitted by the branded drug manufacturer. By changing its use code, thereby misrepresenting to the FDA that the '358 patent covered all three approved uses of repaglinide, Defendants created the requisite overlap between the proposed amended label and the use code to deprive the FDA of its ability to approve Paddock's Section viii Statement.

63. Left with no other option, Paddock filed a Paragraph IV Certification against the '358 patent, mailing notice to Defendants on April 15, 2010.

64. Paddock's Paragraph IV Certification and notice provides the Defendants with jurisdiction to bring a patent infringement suit against Paddock under the Hatch-Waxman Act, and, thus, trigger a 30-month stay of approval of Paddock's ANDA.

65. Defendants brought such a patent infringement suit against Paddock under the Hatch-Waxman Act in the District of Minnesota on May 28, 2010. *Novo Nordisk Inc., et al. v. Paddock Labs., Inc.*, Case No. 0:10-02199 (D. Minn. May 28, 2010).

66. A Section viii Statement, as in Paddock's original filing, would not provide such jurisdiction and would not trigger a 30-month stay.

67. Paddock's Paragraph IV Certification also triggers a separate stay of approval, so that Paddock's ANDA will not be approved until 180 days after the first marketing of the drug by the "first applicant" to file a Paragraph IV Certification. The 180-day exclusivity period not only provides Defendants with 180 days of limited generic competition, but it also allows Defendants to delay entry of all generic applicants as long as it can delay entry of the "first applicant."

68. A Section viii Statement, as in Paddock's original filing, would not trigger this 180-day exclusivity period.

69. But for the Defendants' inconsistent and deliberately misleading misrepresentation of the altered use code to the FDA, Defendants would not have had Hatch-Waxman jurisdiction to bring a patent infringement suit against Paddock, and trigger the 30-month stay of approval, based on the '358 patent. In fact, the U.S. District Court for the District of New Jersey recently dismissed for lack of Hatch-Waxman jurisdiction Defendants' suit against an applicant who filed its ANDA prior to the improper use code change. *See Novo Nordisk, Inc., et al. v. Mylan Pharm., Inc.*, Case No. 3:09-02445 (D.N.J. May 20, 2009).

70. Further, but for the Defendants' inconsistent and deliberately misleading misrepresentation of the altered use code to the FDA, Defendants would not be entitled to the period of limited competition provided by the 180-day exclusivity period.

71. Defendants' manipulation of the FDA use code as described above has unlawfully extended their monopoly on repaglinide, significantly delaying market entry by Paddock and other competitors.

72. Defendants' anticompetitive acts are not entitled to antitrust immunity, including immunity under the Noerr-Pennington doctrine, for, at a minimum, the following independent reasons: (a) the FDA's listing of the use code for '358 patent was a purely ministerial act, and thus Defendants' conduct before the FDA does not constitute legally protected petitioning activity; and (b) the Noerr-Pennington doctrine does not immunize or protect the type of improper and deliberately misleading conduct that Defendants committed before the FDA.

73. Defendants knew that the representations that they made in submitting the use code for the '358 patent Orange Book in connection with Prandin® were inconsistent and deliberately misleading. In fact, Defendants' representations to the FDA relating to the use code for the '358 patent in connection with Prandin® were directly contrary to both (1) the language of the patent itself; and (2) the representations Defendants made to the FDA relating to the use code for the '358 patent in connection with Prandimet®.

THE ANTICOMPETITIVE EFFECTS OF DEFENDANTS' CONDUCT

74. Defendants' anticompetitive practices have had a direct, substantial and adverse effect on Paddock and competition by monopolizing and maintaining monopoly power in the relevant markets, artificially creating barriers to entry in the relevant market, and foreclosing competition.

75. But for Defendants' conduct, Paddock and other generic competitors would have been able to compete for sales within the Relevant Market substantially earlier. Absent Defendants' improper change to their use code, which stripped the FDA of its ability to approve Paddock's Section viii Statement with respect to Prandin®, Paddock and/or other generic manufacturers would have been able to enter the market for repaglinide as soon as they received final approval from the FDA. Instead, Paddock and other generic competitors are foreclosed from entering the market for at least 30 months, while Paddock is forced to litigate infringement of a patent (the '358 patent) that fails to cover the uses for which Paddock intends to market generic repaglinide.

76. Because Paddock's competing repaglinide tablet product would be priced below, and would be an AB-rated equivalent to, Defendants' Prandin®, Paddock would make significant sales immediately upon entry into the Relevant Market.

77. Defendants' anticompetitive conduct has impeded and will delay the sale of generic repaglinide tablets in the Relevant Market, and thus will allow Defendants to maintain and extend their monopoly power in the Relevant Market and to sell Prandin® at artificially inflated monopoly prices.

78. This conduct has harmed the competitive process and allowed Defendants to perpetuate supracompetitive prices from wholesalers, retailers, and consumers.

79. There are no procompetitive justifications, countervailing efficiencies, increases in consumer welfare, or legitimate business reasons for Defendants' conduct.

80. Paddock has extensive experience in the pharmaceutical industry, including obtaining approval for ANDAs and marketing generic pharmaceutical products.

81. Paddock has a history of achieving high approval rates for its ANDAs in relatively short periods of time.

82. Paddock has sufficient financial capacity to enter the Relevant Market.

83. Paddock has taken actual and substantial affirmative steps toward obtaining regulatory approval for its repaglinide tablet product.

84. Paddock has expended substantial labor and sums of money in developing its repaglinide tablet product, and otherwise preparing to enter the Relevant Market.

NEED FOR INJUNCTIVE RELIEF

85. Defendants' conduct has directly, proximately, and foreseeably caused irreparable injuries, or threatens to cause irreparable injury to, Paddock in at least the following ways:

a. Paddock will expend substantial sums to defend itself in a patent infringement litigation regarding the '358 Patent, as well as incur the expenses of this litigation;

b. Paddock stands to lose millions of dollars in profits from lost sales by virtue of its foreclosure from and/or delayed entry into the Relevant Market; and

c. Paddock is losing valuable goodwill due to the competitive disadvantage resulting from its foreclosure from and/or delayed entry into the Relevant Market.

86. Defendants' conduct has continuing harmful effects, and without the intervention of the Court, Paddock faces continuing and irreparable damage and injury from its continued exclusion from the Relevant Market.

87. The injuries to the public interest through the delayed entry of generic repaglinide products are not susceptible to an adequate remedy through money damages.

88. Paddock currently does not know the full extent of its threatened damages, but it is believed that the total damages resulting from the unlawful conduct alleged herein will be substantial. Paddock reserves the right to amend the present Complaint at such time as Paddock has ascertained more precisely the full extent of its actual and threatened damages.

89. The actual and threatened injury to competition flows directly from Paddock's actual and threatened injuries, and both Paddock's actual and threatened injuries and the actual and threatened injury to competition result from Defendants' anticompetitive conduct.

90. The actual and threatened injury to Paddock resulting from Defendants' wrongful conduct constitutes antitrust injury.

FIRST CLAIM FOR RELIEF

Monopolization (Sherman Act § 2)

91. Paddock repeats and realleges Paragraphs 1 to 90 as though fully set forth herein.

92. At all relevant times, Defendants have possessed monopoly power in the Relevant Market.

93. During the relevant period, Defendants have willfully and unlawfully maintained and extended their monopoly power by making inconsistent and deliberately misleading misrepresentations to the FDA. Defendants improperly changed the use code for the '358 patent and, in doing so, (1) incorrectly misrepresented to the FDA that the '358 patent covered all three approved methods of use for repaglinide, when in fact Defendants knew that the '358 patent claimed only a method of using repaglinide in combination with metformin, (2) deliberately made this incorrect misrepresentation to the FDA with the intent and effect of delaying generic competition to its Prandin® monopoly from Paddock and other generic ANDA filers for Prandin® that sought to market repaglinide itself—a use that does not infringe the '358 patent or any other unexpired patent, and (3) inconsistently represented (and still represents) to the FDA two different use codes for the '358 patent—one for Prandin® and one for Prandimet®—despite the fact that the '358 patent claims only one method of use.

94. Defendants' conduct was intended to suppress rather than promote competition on the merits, and has had precisely the intended effect.

95. Defendants' conduct has had anticompetitive effects in the Relevant Market by impeding and delaying the sale of generic repaglinide tablets in the Relevant Market, and thus allowing Defendants to sell Prandin® at artificially inflated monopoly prices.

96. Defendants' conduct occurred in and is having a substantial effect on interstate commerce.

97. Paddock's injury is an injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

98. Defendants' conduct threatens continuing loss and injury to Paddock unless enjoined by the Court.

99. Paddock is entitled to injunctive relief to prevent its threatened injury and damages.

100. Permanent injunctive relief is necessary to prevent threatened antitrust injury to Paddock.

SECOND CLAIM FOR RELIEF

Attempted Monopolization (Sherman Act § 2)

101. Paddock repeats and realleges Paragraphs 1 to 100 as though fully set forth herein.

102. At all relevant times, there has been a dangerous probability of Defendants achieving monopoly power.

103. During the relevant period, Defendants have willfully and unlawfully attempted to obtain, maintain, and extend their monopoly power by making inconsistent and deliberately misleading misrepresentations to the FDA. Defendants improperly changed the use code for the '358 patent and, in doing so, (1) incorrectly misrepresented to the FDA that the '358 patent covered all methods of use for repaglinide, when in fact Defendants knew that the '358 patent claimed only a method of using repaglinide in combination with metformin, (2) deliberately made this incorrect misrepresentation to the FDA with the intent and effect of delaying generic competition to its Prandin® monopoly from Paddock and other generic ANDA filers for Prandin® that sought to market repaglinide for use as a monotherapy only—a use that does not infringe the '358 patent or any other unexpired patent, and (3) inconsistently represented (and still represents) to the FDA two different use codes for the '358 patent—one for Prandin® and one for Prandimet®—despite the fact that the '358 patent claims only one method of use.

104. Defendants' conduct was intended to suppress rather than promote competition on the merits, and has had precisely the intended effect. Defendants have a specific intent to monopolize, and have taken affirmative exclusionary steps in furtherance of their attempt to monopolize the Relevant Market.

105. Defendants' conduct has had anticompetitive effects in the Relevant Market by impeding and delaying the sale of generic repaglinide tablets in the Relevant Market, and thus allowing Defendants to sell Prandin® at artificially inflated monopoly prices.

106. Defendants' conduct occurred in and is having a substantial effect on interstate commerce.

107. Paddock's injury is an injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

108. Defendants' conduct threatens continuing loss and injury to Paddock unless enjoined by the Court.

109. Paddock is entitled to injunctive relief to prevent its threatened injury and damages.

110. Permanent injunctive relief is necessary to prevent threatened antitrust injury to Paddock.

THIRD CLAIM FOR RELIEF

Monopolization (Michigan Antitrust Reform Act, Section 445.773)

111. Paddock repeats and re-alleges the allegations of paragraphs 1 to 110 as if fully set forth herein.

112. This count is brought pursuant to the Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.773.

113. Defendants have engaged in acts that established, maintained or used a monopoly or an attempt to establish a monopoly of trade or commerce in the Relevant Market.

114. The purpose of Defendants' conduct was the exclusion of competition in the Relevant Market.

115. Defendants' conduct has affected trade or commerce, which occurred in part within the State of Michigan.

116. Paddock will sustain damages as a direct and proximate result of Defendants' exclusionary conduct.

117. Paddock is entitled to recovery for its damages.

PRAYER FOR RELIEF

WHEREFORE, Paddock respectfully prays that the Court enter judgment against Novo Nordisk, Inc. and Novo Nordisk A/S and in favor of Paddock, as follows:

1. Entering a judgment that Defendants have violated Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2;

2. Entering a judgment that Defendants have violated the Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.773;

3. Awarding permanent injunctive relief enjoining Defendants from continuing its illegal conduct and requiring Defendants to affirmatively dissipate the effects of its prior and ongoing violations, including:

   i. Compelling Defendants to correct the use code for Prandin®, and to reinstate the earlier U-546 use code describing the '358 patent as covering the "use of repaglinide in combination with metformin to lower blood glucose," and

   ii. not undertaking any additional conduct that could delay or impede generic entry in the Relevant Market;

4. Entering an Order, pursuant to the Sherman Antitrust Act, 15 U.S.C. § 2, *et seq.*, the Clayton Act, 15 U.S.C. § 15, and the laws of Michigan, awarding damages, costs of suit, interest and attorneys fees to Paddock, and that Paddock's damages be trebled;

5. Awarding Paddock such further equitable relief as may be reasonably likely to cure the threatened harm to Paddock and to competition in the Relevant Market caused by Defendants' conduct; and

6. Awarding Paddock such further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Paddock demands a trial by jury for all issues triable by jury.

Respectfully submitted,

DYKEMA GOSSETT PLLC

By: /s/ Thomas M. Schehr

Thomas M. Schehr (P54391)
Nasseem S. Ramin (P73513)
Attorneys for Plaintiffs
400 Renaissance Center, 35th Floor
Detroit, MI 48243
313-568-6659 or 313-568-5326
tschehr@dykema.com
nramin@dykema.com

and

Daniel G. Brown
Gina R. Gencarelli
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
1301 Avenue of the Americas, 40th Floor
New York, NY 10019
Telephone: (212) 999-5800
Facsimile: (212) 999-5899

Seth C. Silber
Jonathan R. Lutinski
WILSON SONSINI GOODRICH & ROSATI
Professional Corporation
1700 K Street, N.W., 5th Floor
Washington, D.C. 20006
Telephone: (202) 973-8800
Facsimile: (202) 973-8899

Attorneys for Plaintiff
Paddock Laboratories, Inc.

Dated: July 13, 2010